510(k) Summary of Safety and Effectiveness

1. Sponsor Name

Magna-Lab, Inc.
Six Kimball Lane, Suite 210
Lynnfield, MA 01940
Telephone: 781-246-4774
Contact Individual: John Geisel

2. Device Name

Illuminator™ Automatic Tune Box and Interface Cable (ATIB)

3. Identification of Predicate or Legally Marketed Device

The Automatic Tune Interface Box (ATIB) is substantially equivalent to the manual tune interface unit cleared under K010513 for the Transesophageal Probe and K010802 for the Surface Coil.

4. Device Description

The Illuminator™ Automatic Tuning Interface Box (ATIB) provides an interface for the Illuminator™ Transesophageal Probe, the Illuminator™ Surface Coil and the General Electric 1.5 T Signa® Magnetic Resonance Imaging (MRI) Systems. The device automatically tunes the Transesophageal (TE) Probe and matches the impedance of the probe to the interface of the MRI system. The Auto Tune Interface Box will be used in clinical MRI rooms. The interface box interfaces with the GE MRI machine through a cable bundle with a 30 pin connector box attached.

5. Intended Use

The intended use of the Illuminator™ Automatic Tune Interface Box and Interface Cable is for high resolution Magnetic Resonance Imaging (MRI). It is used in conjunction with the Magna-Lab TE Probe and Surface Coil.

6. Comparison of Technological Characteristics

The manual tune box is replaced by the auto tune box and cable, and the design and materials have not changed in any substantial way.

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Integrating the ATIB into the Illuminator™ Transesophageal Probe system does not alter or change its intended use. It is substantially equivalent to its predecessor, Transesophageal Probe (with manual tune box), the only difference being that the auto tune box automatically matches and simplifies the electrical impedance tuning process.

7. Performance Testing

Magna-Lab has performed testing and/or analysis of the Interface Box. This testing includes the following:

- Imaging performance comparisons between the manual tune and auto tune interface units.
- Signal to Noise Comparisons
- Temperature Measurements

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2002

Mr. John R. Geisel
Chief Executive Officer
Magna-Lab, Inc.
Six Kimball Lane, Suite 210
LYNNFIELD MA 01940

Re: K020993
Trade/Device Name: Illuminator™ Automatic Tune Box and Interface Cable (ATIB)
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: 90 MOS
Dated: March 22, 2002
Received: March 27, 2002

Dear Mr. Geisel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

MAGNA-LAB INC.

510(k) Number (if known): K020993

Device Name: Illuminator™ Automatic Tune Box and Interface Cable (ATIB)

Indications For Use:

The intended use of the Illuminator™ Automatic Tune Interface Box and Interface Cable is for high resolution Magnetic Resonance Imaging (MRI). It is used in conjunction with the Magna-Lab TE Probe and Surface Coil.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

David A. Segmon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020993

Confidential